

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/)	
FENFLURAMINE/DEXFENFLURAMINE))	MDL NO. 1203
PRODUCTS LIABILITY LITIGATION)	
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THIS DOCUMENT RELATES TO:)	
SHEILA BROWN, et al.)	
v.)	CIVIL ACTION NO. 99-20593
AMERICAN HOME PRODUCTS)	
CORPORATION)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 8880

Bartle, J.

May 30, 2012

Deborah L. Brown ("Ms. Brown" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,¹ seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").²

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did
(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney completes Part III if claimant is represented.

In April, 2003, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Stephen Raskin, M.D., F.A.C.C. Dr. Raskin is no stranger to this litigation. According to the Trust, he has attested to at least 84 Green Forms on behalf of claimants seeking Matrix Benefits. Based on an echocardiogram dated July 10, 2002, Dr. Raskin attested in Part II of Ms. Brown's Green Form that she suffered from moderate mitral regurgitation and a reduced ejection

2. (...continued)

not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

fraction in the range of 50% to 60%.³ Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of \$522,266.⁴

In the report of claimant's echocardiogram, the reviewing cardiologist, Niel F. Starksen, M.D., F.A.C.C., stated that claimant had "moderate mitral regurgitation (2+)." Dr. Starksen, however, did not specify a percentage as to the level of claimant's mitral regurgitation. Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22.

In June, 2006, the Trust forwarded the claim for review by Nancy I. Streitmatter, M.D., one of its auditing cardiologists. In audit, Dr. Streitmatter concluded that there was no reasonable medical basis for the attesting physician's

3. Dr. Raskin also attested that claimant suffered from mild aortic regurgitation and New York Heart Association Functional Class I symptoms. These conditions, however, are not at issue in this claim.

4. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust does not contest the attesting physician's finding of a reduced ejection fraction, which is one of the complicating factors needed to qualify for a Level II claim, the only issue is claimant's level of mitral regurgitation.

finding that claimant had moderate mitral regurgitation because her echocardiogram demonstrated only mild mitral regurgitation. Dr. Streitmatter explained, "Visually [the mitral regurgitation] is mild, less than 1/6th the area of the left atrium."

Based on the auditing cardiologist's finding that claimant had mild mitral regurgitation, the Trust issued a post-audit determination denying Ms. Brown's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.⁵ In contest, claimant argued that there was a reasonable medical basis for Dr. Raskin's representation of moderate mitral regurgitation. In support, Ms. Brown submitted an affidavit from Dr. Raskin, wherein he stated:

The 2003 ASE document rejects the AHP Trust methodology of planimetry (or "eye-balling") of the [mitral regurgitant] color flow jet area as a sole determinant of [mitral regurgitation] severity. Nevertheless, to accurately evaluate the [mitral regurgitation] grade as dictated by the AHP [T]rust further comments based on the color jet are imperative.

....

5. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Brown's claim.

.... Specific care was made to prevent any over representation of the [mitral regurgitant] jet such as avoidance of random inclusion of light blue low velocity flow, entrained flow, as well as any possible pulmonary venous flow from the RJA. Additionally, the [mitral regurgitant] jet boundary in this case was traced with care to avoid including black (no color) areas of the [left atrium]. In summary, the mitral RJA/LAA ratio is 24% and the degree of mitral regurgitation is consistent with moderate as defined by the AHP Trust.

(internal citation omitted). Dr. Raskin attached several still frames that purportedly demonstrated his findings.

Although not required to do so, the Trust forwarded the claim to an additional auditing cardiologist, Craig M. Oliner, M.D., for a second review. Dr. Oliner concluded:

There is no real time color [D]oppler imaging of [mitral regurgitation] in any apical view. The [mitral regurgitation] is mild in the [parasternal long-axis view] view. The spectral [D]oppler [mitral regurgitation] is weak suggesting mild [mitral regurgitation]. The single freeze frame in the apical view shows a mixture of [mitral regurgitation] and non-[mitral regurgitation] signal. The [mitral regurgitation] is mild.

The Trust then issued a final post-audit determination, again denying Ms. Brown's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to Show Cause why Ms. Brown's claim should be paid. On

February 15, 2007, we issued an Order to Show Cause and referred the matter to the Special Master for further proceedings. See PTO No. 6971 (Feb. 15, 2007).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on June 1, 2007. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor⁶ to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Sandra V. Abramson, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a

6. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

reasonable medical basis for the attesting physician's finding that she had moderate mitral regurgitation. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

The Technical Advisor, Dr. Abramson, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's finding that Ms. Brown had moderate mitral regurgitation. Specifically, Dr. Abramson explained that:

I reviewed the transthoracic echocardiogram from 7/10/02. It is an inappropriately abbreviated, incomplete study. In the parasternal long-axis view, there are two sets of images containing two cardiac cycles in each image, demonstrating mild mitral regurgitation. In the apical views, there is only one frozen frame demonstration of mitral regurgitation. There are no real time continuous loop images of the mitral regurgitation. Thus, it is impossible to determine a 'representative' cardiac cycle in the apical views. Despite this, I tried to obtain a RJA/LAA ratio. I measured the left atrial area of 21.8cm² in a different cardiac cycle since the frame with the color flow imaging was angled to accentuate the mitral regurgitation, which

cut off the left atrium. I measured this one mitral regurgitant jet area of 3.0cm². The RJA/LAA ratio = 14% which is consistent with mild mitral regurgitation. This one cardiac cycle at meter 16:07:26-16:07:27 is the same meter number of the four photographs that are submitted in the records....

In summary, the quantitative assessment of the severity of this claimant's mitral regurgitation is based on one frozen cardiac cycle in the apical views, which agrees with the qualitative assessment of the four cardiac cycles in the parasternal long axis view. Assuming they are representative cycles, this study demonstrates only mild mitral regurgitation. There is no reasonable medical basis for the Attesting Physician's claim that this patient has moderate mitral regurgitation, based on the echocardiogram of 7/10/02. This study demonstrates that Deborah L. Brown has only mild mitral regurgitation.

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. Contrary to claimant's contention, Dr. Raskin's opinions do not provide a reasonable medical basis for his representation that Ms. Brown has moderate mitral regurgitation. We previously have stated that still frames alone are not sufficient to determine a claimant's level of mitral regurgitation. See, e.g., PTO No. 6897, at 7 (Jan. 26, 2007) (further citation omitted). Here, Dr. Abramson observed that the echocardiogram was "inappropriately abbreviated" and "incomplete." Specifically, she determined that the echocardiogram did not include real time continuous loop images and included only one freeze frame demonstrating mitral

regurgitation.⁷ In addition, Dr. Oliner noted only a "single freeze in the apical view." Such unacceptable practices cannot provide a reasonable medical basis for the resulting diagnosis and Green Form answer.

We also disagree with claimant's arguments concerning the required method for evaluating claimant's level of valvular regurgitation. Although the Settlement Agreement specifies the percentage of regurgitation needed to qualify as having moderate mitral regurgitation, it does not specify that actual measurements must be made on the echocardiogram. As we explained in PTO No. 2640, "'[e]yeballing' the regurgitant jet to assess severity is well accepted in the world of cardiology." See id. at 15. Claimant essentially requests that we write into the Settlement Agreement a requirement that actual measurements of mitral regurgitation be made to determine if a claimant qualifies for Matrix Benefits. There is no basis for such a revision and claimant's argument is contrary to the "eyeballing" standards we previously evaluated and accepted in PTO No. 2640.⁸

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable

7. Despite an opportunity to do so, claimant did not submit a response to the Technical Advisor Report. See Audit Rule 34.

8. Claimant's argument also fails because the Technical Advisor, although not required to, made a specific measurement of the level of Ms. Brown's mitral regurgitation, which further establishes that claimant is not entitled to Matrix Benefits.

medical basis for finding that she had moderate mitral regurgitation. Therefore, we will affirm the Trust's denial of Ms. Brown's claim for Matrix Benefits.